The Development of a National Approach to CDA: Successes, Challenges, and Lessons Learned from Australia

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Abstract

Background: Australia has been in the process of designing and implementing a national ehealth system for a number of years. A core component of this design has been the selection of HL7's CDA as the basis of the Australian EHR. This incorporates CDA into both the shared Personally Controlled Electronic Health Record and for document exchange point-to-point. **Objectives:** CDA was chosen partly for its ability to address issues of governance and consistency in a national environment that does not have definitive oversight or a single decision making body. **Methods:** Developing long and complex implementation guides has been assisted by good design of a 'super-schema' to include the Australian extensions, together with a framework for extensive conformance checking. Australia has created a multi-level conformance framework which currently supports a mainly Level 2 CDA architecture yet provides a transition pathway to future full interoperability. **Results:** One area of contention around the Australian solution, however, is debate over content presentation and data content using CDA. The Australian implementation has had considerable debate around the technical and governance infrastructure for controlling the rendering of the documents. Other challenges have arisen in the selection of transport standards, sourcing of CDA expertise and in relation to the need for local extensions to CDA. Local extensions to CDA have been modelled using the HL7 development paradigm (based on the HL7 RIM) as permitted by the CDA standard, and submitted for inclusion in HL7 CDA Release 3. **Conclusions:** This paper illustrates the Australian approach to the development of CDA for the National EHR and ehealth point-to-point communications, and provides an insight for other countries considering similar implementations.

Keywords

Medical Informatics Computing, Health Communication, Data Sharing, Health Level 7.

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1 Introduction

In the development of the national ehealth system, Australia has focussed on an open standards approach to facilitate interoperability in an open market [1]. This approach is driven by the duality of the Australian health care system that embraces both private and public sector health delivery, and the overall complexity of the health care system delivered by a complex multilateral partnership between Australia's States, Territories, and the Australian Federal government.

HL7 Clinical Document Architecture Release 2 (CDA)

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is a document mark-up standard that specifies the structure and semantics of clinical documents for the purpose of exchange and unambiguous interpretation both at human and system levels. Among its primary advantages are that it is both machine computable and human readable and provides a standardised display of clinical information without loss of clinical meaning.

The CDA standard divides the document content into two sections, a human readable text section (narrative) and a computable structured section (structured entries) using coding systems such as SNOMED-CT to represent data concepts. It uses extensible mark-up language (XML) to guarantee the preservation of the content. CDA is designed to be transport method and platform independent.

The representation semantically of clinical documents is an integral part of the HL7 Version 3 family of messaging formats and architecture. It was ANSI approved in 2000. It allows a method to use flexible free text clinical notes whilst providing a structure to enable comparison of documents based on the underlying information model and semantic encoding by utilising standard healthcare terminologies. Multimedia content such as images and sounds along with text can be incorporated.

The structure of the CDA document is broken into two main parts: the header and the body. The header contains information that identifies and classifies the document and provides information on authentication, the encounter, the patient and the involved providers. The body contains the clinical content. The body containing the clinical report can be unstructured or can be defined using a structured mark up template. There are three levels of hierarchy in CDA. Level 1 is largely narrative text within the document with no computer processable structured data. Level II incorporates a structured narrative broken into sections. Level III additionally includes formal expressions of the clinical content using coding and explicit data representations. Whilst the clinical content will remain constant, the level of computability and machine processing distinguishes between the three levels [2]. CDA also provides the essential characteristics of persistence, governance (stewardship), authentication, completeness and human readability that ensure interoperability and clinical usefulness in the electronic health care record environment [3].

Australia is in the process of implementing CDA for electronic transfer of prescriptions (ETP) and for continuity of care. These will form part of the national Personally Controlled Electronic Health Record (PCEHR) which is due to start in 2012. CDA document types being used are a General Practice Shared Health Summary (SHS), a generic document for recording clinical events (Event Summary), a Document to carry information from a medical specialist back to a referring doctor (Specialist Letter), a hospital Discharge Summary and a general medical Referral document. For application into national and localised contexts CDA accommodates CDA standards compliant local extensions. It is these extensions and other issues related to the CDA documents themselves and their implementation that this paper addresses, based on the Australian context. This leads to a discussion of the challenges that have resulted from the adoption of CDA into Australian healthcare and the learning that can be shared to assist other countries in their adoption and use of CDA.

2 CDA for Australia

CDA has been used as the basis of the Australian EHR. All the content provided to the PCEHR is provided in the form of CDA documents. The decision on the use of CDA and the ramifications of this are related to governance, appropriate use, complexity, conformance and data presentation.

2.1 Governance

CDA was chosen as the basis for the Australian EHR for multiple reasons. CDA was chosen because it was useful for Australia to build on "extensive implementation experience, standards development work, tooling and vendor capability arising from use of HL7 v3 and CDA R2 in major programs, including those of Connecting for Health (CfH) in the UK, Canada Health Infoway, US Government health agencies, RHIOs and the IHE consortium" [4]. It provided a sound basis for the ongoing development of interchange formats across domains. It also supported the existing paper based documentation for easier translation to the electronic environment. In addition, CDA was chosen partly to address the issues of governance and consistency. In Australia there is no 'governing authority' that is in a position to make decisions about clinical terminologies, representation, understanding, and workflow. Unfortunately, given the lack of coherent management to define a consistent and complete content of an Australian EHR, there is little short to medium prospect that a coherent medical record can be built in Australia. Under such circumstances, the most that can be hoped for is a series of related documents, and that from this a longer term platform for clinical coherence may be built.

2.2 Appropriate Use

CDA was chosen as the general purpose tool for the content of the Australian PCEHR. A large national program such as this needs architectural consistency and because there has been a substantial investment in tooling and validation methods, along with development of an eco-system and a community around CDA, there is considerable pressure to use CDA as the basis for all information in the system. However, CDA itself is not intended to solve all the clinical representation problems encountered by a national EHR program, and there is therefore a disconnection between sound architectural principles and proper use of the CDA standards. In Australia this manifests in the proposal to use CDA to capture all clini-

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cal data including where other technology may be more appropriate e.g. ETP dispense notifications and billing records. The lack of understanding between the relative roles and uses of electronic messages, services, documents and electronic workflow and transactions, and real world disagreement about workflow and obligations, has created much confusion in this area.

2.3 Complexity

Paradoxically, CDA has proven both too complex and also too simple. In terms of modelling, without a consistent way of ensuring vendors utilise the logical models in the development of CDA outputs, it will be a very difficult task for many small vendors to produce CDA that is conformant. Many of the PCEHR trial sites are already finding that vendors are having difficulty with the complexity and abstract nature of the CDA standard. Indeed in the Northern Territory, many vendors are finding it difficult to be conformant with the header details, let alone any clinical content.

The Australian process featured extensive requirements and informatics analysis upstream of the CDA documents, and mapping the agreed content to CDA was only performed towards the end of the process. This resulted in a reduced emphasis on alignment with the rest of the world when the analysis and modelling was performed. As a consequence, there is limited consistency between the Australian CDA documents and specifications such as HL7's Consolidated CDA Templates. In some cases, this is an appropriate reflection of Australian requirements, and in other cases, it is product of insufficient alignment early in the process.

In addition, the Australian requirements and modelling process is based on openEHR which is a different complex semantic paradigm, and as a result a considerable part of the mapping from the logical model to the CDA document is arbitrary. Further, CDA is limited, particularly around the restricted set of choices of act relationship codes. In practice, the clinical statement is a hybrid of self-defining RIM statements, and pointers to knowledge expressed in narrative in the implementation guides, and it is not possible to implement the CDA documents properly without consulting the implementation guides.

In terms of complexity, the CDA documents are a language in which the content can be expressed, rather than an expression of the content directly. This leads to long implementation guides and ideally requires that an implementer should read the entire set of logical and technical specifications with accompanying documentation. This is in the order of 10,000 pages (CDA standard, business analysis documents, logical models, CDA implementation guides, conformance rules, test data sets, rendering rules, and CDA/XDS mappings) spread across five CDA document types. Much of this content is repetitive and unfortunately much of the essential reading is interspersed throughout the repetitive documents. There is also an inherent tension between writing a document that suits an implementation that is going to implement all the different clinical document types, and an implementation that is only implementing one of them – the first wants a single document that discusses the differences between the variations, while the second wants a focused document that describes the solution to a single use case.

However, one positive outcome, due to well designed and effective modelling, is that the Australian program offers a single schema that includes all the CDA content that any of the document types might use together with all the Australian extensions. This has been labelled the "super-schema". Users of the super-schema can be assured that any code generated from the super-schema will read any documents that conform to the CDA implementation guides. However it does not cater for all documents, because many of the actual implementations have used extensions. This is consistent with the CDA specification itself, but does not work well with schema. This has caused ongoing difficulties due to the pervasive nature of extensions (see below). In addition, the fact that there is no direct schema expression of the different clinical document types means that there is ongoing confusion about the contents of the document. The National eHealth Transition Authority (NeHTA), the body responsible for the development of the architectural design of the national ehealth system and PCEHR, closely examined several non-standard alternatives to CDA for clinical data representation. These would have allowed direct expression in XML with schema support. However, ultimately CDA was chosen as a standards based alternative.

2.4 Conformance

NeHTA has invested heavily in a schematron based conformance system for checking that CDA documents conform to the specification. The schematron framework performs extensive checking on the document contents to ensure that they fully comply with the specifications in the implementation guide. These schematron rules will be automatically applied to all documents uploaded to the national electronic health record. However, the overall lack of clinical consistency between the different authors and systems across Australia means that in practice, many exemptions have had to be granted. Thus the restrictions on valid content are not as tightly constrained as required. For instance, the documents specify the use of SNOMED-CT for the primary clinical codes, however, few systems are using SNOMED-CT codes. As a consequence, the system is forced to accept other clinical codes for the first phase of implementation. This creates long-term issues in semantic consistency and in semantic interoperability.

The outcome of this is a systematic approach to conformance requirements as summarised in Table 1.

These multiple approaches to conformance provide a framework for a transition pathway to full interoperability. In practice, most document providers are aiming for level

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Table 1: Australian CDA conformance requirements.

Base Specification	A CDA implementation guide that specifies a fully populated document with multiple nested sections, where each section has specified semantics in the narrative, and fixed data in the entries, with specified terminologies for the codes
Level 3B	A fully conformant document, with sections, entries, and codes as specified
Level 3A	A document that has the sections and entries as specified, but codes can from any coding system rather than those specified
Level 2	A document laid out with the sections and narratives as specified, but one that doesn't meet the structured data requirements
Level 1B	A document that contains narrative that meets the general contents for the document type, and that may be broken into some sections
Level 1A	A document that contains a PDF instead of CDA narrative, where the PDF meets the general requirements for the content of the document

2 conformance. This is because the level is declared for an entire document, and the document is checked against the level of conformance that it declares. If a document claims level 3 conformance, the level 3 rules are enforced across the entirety of the document. In practice, many implementations are a few fields short of full compliance. It should be noted that in all levels, supplementary sections for additional data may be introduced into the document. Additionally, within the existing sections, extensions to cater for data not described in the implementation guides are allowed (whether they are standard CDA elements or CDA extensions). This extensibility has proven critical to integrating national EHR support into local clinical exchange practices which have their own pre-existing exchange requirements and practices.

2.5 Data Versus Presentation

In spite of the fact that most documents are aimed at level 2 conformance, considerable work goes into providing a complete document with the capability to represent all the data that can be made available on the part of the authors. The duality of CDA documents, being the delineation between the narrative and data elements, has continued to be a concern for many. Yet, these concerns are mitigated by the fact that existing Australian standards mandate both atomic data and presentation formats for clinical documents, and the Australian CDA solutions are closely aligned to these existing approaches. It should also be recognised that CDA documents are now being used to provide interoperability in areas where clinical exchange has not been widely used before. This creates uncertainty about how much narrative or data based interoperability will be possible or useful in current Australian clinical practice. This is an issue that can only be resolved as the ehealth system is introduced. Future changes to the specifications should be expected as experience is gained in Australia.

One area where the narrative/data duality, together with the presence of extensions, has had a particularly pronounced effect is in the overall architecture of the program. In particular, the degree to which the system can be leveraged to provide enhanced summary clinical views. The potential presence of a large amount of available data has provided a tantalising suggestion that a useable summary view can be presented, but any coherent plan for such a view founders on the poor consistency of the data, and the presence of narrative and extensions. The Australian ehealth program will continue to work to improve the clinical and technical consistency of the document to enable summary views, decision support, and in the longer term (once privacy and data governance issues are resolved), secondary use for analysis.

Finally, document authors have felt strongly about how the documents are presented. Generally, the Australian document providers have approached their CDA implementations with some reluctance and there is still a strong preference for the use of PDF. Though PDF is much less useful for subsequent processing, PDF is a controlled presentation with less variables (though not none) than a CDA document. There is ubiquitous concern that the processability of the narrative will lead to the reprocessing of the narrative, and that this possibility creates liability concerns for the author. As a consequence, the national program has invested a great deal of effort into developing a rendering specification that clearly describes the obligations of both authors and renderers to ensure that a document is displayed correctly.

3 Associated Issues for Australian CDA Adoption

Issues related to, but not directly as a result of, the CDA documents themselves have also required consideration in the use of CDA in the Australian healthcare environment. These relate to the transport mechanisms selected and the workforce required for CDA.

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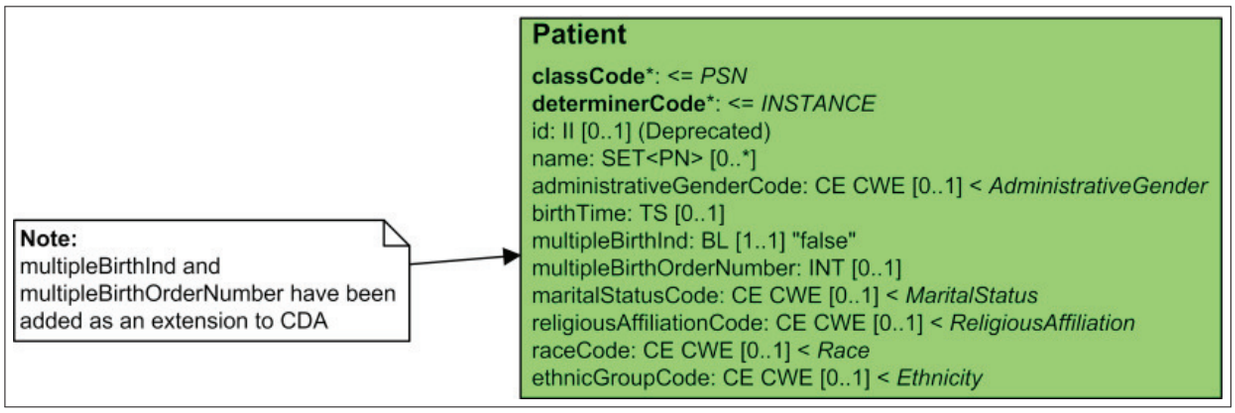

Figure 1: Example of Australian extension to CDA

3.1 Point-to-Point Exchange

Whilst the national EHR is based on IHE XDS.b, it is also intended that the CDA documents that have been developed for that purpose, should be usable in point to point document exchange. Australia has developed a local standard which is a profile of Internet standards that provides a means of sending an encrypted package point–to-point in a secure and reliable manner. This is called Secure Message Delivery (SMD – AS 5822-2010) – it is content agnostic and provides transport level acknowledgements. The CDA standard describes how CDA documents can be transported by embedding the CDA content within a specialised HL7 V2 segment. The Australian national program has leveraged this approach and chosen the generic HL7 MDM message to carry CDA content point-to-point. Whilst this provides generic document triggers and acknowledgements, it does not provide content specific triggers or acknowledgements required for complex clinical scenarios involving patient inter-provider referral. This makes it difficult to implement clinical workflows when exchanging documents rather than messages.

This issue is also of importance when complex clinical workflows such as Electronic Transfer of Prescriptions (ETP) are being specified using CDA content. It is necessary to find other means than a static, unchangeable document to manage state and state transition triggers required by such workflows. IHE has undertaken this for ETP as part of the EPSOS project but it has proven challenging.

The issue of appropriate acknowledgements for CDA content and introduced potential clinical risks by their absence, is yet be addressed in the Australian context and is likely to limit the uptake of CDA in contexts where workflow is an important element.

Another issue related to point-to-point exchange has been around the way that attachments and electronic signatures are handled. The CDA specification itself lays down some basic principles that severely restrict the kinds of solutions that are possible. To handle this, the national program was forced to specify a full set of CDA packaging rules, which specifies a particular way of attaching images to CDA, and to do digital signatures. Both the logical and technical approach took many months and iterations to achieve convergence. This is complicated by the approach that the IHE specifications take, which is different.

3.2 Workforce Issues Related to CDA

Australia has a small pool of CDA expertise and the cost of acquiring training and experience with CDA is high due to the requirement to access this from the USA and Europe. Competition for such a limited pool of workers has hampered the ability to develop and maintain high quality CDA specifications and implementation guides which are consistent across a wide range of clinical domains.

With the imminent roll-out of a national CDA based infrastructure, the ehealth vendor community has upgraded its workforce's skills considerably in order to implement and maintain CDA based versions of their clinical software, but capacity is still short of what is required. The ability of the small team that have successfully developed a national CDA capability is also now being sought out by other international groups interested in pursuing a similar direction. This will further exacerbate the Australian skill shortage and force up costs of retaining this critical workforce.

4 Technical and Content Challenges

4.1 CDA Constraints and Extensions

Because CDA is a set of constraints on the HL7 RIM, there are sometimes cases where local semantics have no corresponding representation in the CDA specification. CDA provides a mechanism for handling this. Implementation guides are allowed to define extensions, provided some key rules are followed:

- Extensions must have a namespace other than the standard HL7v3 namespace;

- The extension cannot alter the intent of the standard CDA document. For example, an extension cannot be used to indicate that an observation does not apply where the CDA document requires it; and
- HL7 encourages users to apply for formalisation of their specific requirements into a subsequent version of the standard. This is to maximise the use of shared semantics.

For application into the Australian environment, a number of extensions to CDA have been defined. To maintain consistency, the same development paradigm has been adopted as that used to develop CDA. Subsequently, most Australian extensions have been submitted to HL7 for inclusion into a future release of CDA (Release 3 currently under development).

All Australian extensions to CDA are based on the HL7 RIM. This is not an HL7 requirement of extensions but was a considered a prudent approach as it ensures Australia is future-proofed when CDA R3 arrives and ensures that the extensions are properly modelled (based on existing HL7 domain models) rather than injected into inappropriate CDA elements/attributes. Using inappropriate CDA elements/attributes is syntactically correct but not necessarily semantically correct. Figure 1 gives an example of the extension for Multiple Birth Order Number.

The Australian national Health Identifier (HI) Service requires that multiple birth order number be sent with all clinical documents that need identification through the service. multipleBirthInd and multipleBirthOrderNumbers are underlying RIM elements of the LivingSubject class (the Person class is a specialisation of LivingSubject), however, these elements have been constrained out of CDA. The Australian specifications have removed this constraint and returned the elements to the CDA structure.

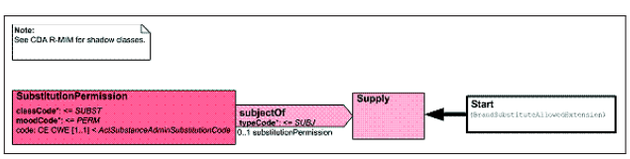

Figure 2: Preferred modelling of Brand Substitute Allowed CDA extension.

A second example, shown in Figure 2, shows the Australian modelling of the data structure for "Brand Substitute Allowed". The requirements for the Australian Electronic Transfer of Prescription (ETP) stipulate the inclusion of the concept "Brand Substitute Allowed". The definition of this concept is: "indicates whether or not the substitution of a prescribed medication with a different brand name or generic drug, which has been determined as bioequivalent, is allowed when the medication is dispensed/supplied" [5]. After consultation with the HL7 Pharmacy Working Group it was determined that the semantically correct way to model "Brand Substitute Allowed" was as it was modelled in the Normative Medication Order R-MIM [6]. Due to the fact that it is not 'legal' to extend the CDA vocabulary (classCode=SUBST and moodCode=PERM), an Australian extension was added to CDA.

```
<ext:subjectOf2>
  <ext:substitutionPermission classCode="SUBST" moodCode="PERM">
    <ext:code
      code="TE"
      codeSystem="2.16.840.1.113883.5.1070"
      codeSystemName="HL7:SubstanceAdminSubstitution"
      displayName="Therapeutic"/>
  </ext:substitutionPermission>
</ext:subjectOf2>
```

Figure 3: CDA XML representation of Brand Substitute Allowed Extension

The advantages of the representation in Figure 3 include:

- Derived from HL7 "MedicationOrder";
- Stated to be the "semantically correct" solution by HL7; and
- Meaning is clear from the classCode of SUBST (Substitution) and the moodCode of PERM (Permission).

The disadvantages are:

- Needs to be in another namespace (as defined by HL7 in its rule for extensions). This is not a significant disadvantage in the Australian space, as there are more than just this one extension and they are all in the same namespace. In fact, the HL7 Consolidation Templates (US Realm) also employ extensions (as do others internationally) so this is not an unusual choice; and
- Adding these extensions to the schema has created confusion because the schema implies that the extensions are added to the base role or entity, even though they are only applicable to a sub-class of role or entity. The schema is not capable of expressing the notion that these extensions are only used with the appropriate class codes.

An alternate way to model the "Brand Substitute Allowed" concept without using a local extension to CDA is a method previously considered by IHE (see [7]).

```
<entryRelationship typeCode="SUBJ" inversionInd="true">
  <observation classCode="OBS" moodCode="EVN">
    <code code="SUBST"
          displayName="Substitution"
          codeSystem="2.16.840.1.113883.5.6"
          codeSystemName="HL7 ActClass"/>
    <value xsi:type="CE"
           code="TE"
           displayName="Therapeutic"
           codeSystem="2.16.840.1.113883.5.1070"
           codeSystemName="HL7:SubstanceAdminSubstitution"/>
  </observation>
</entryRelationship>
```

Figure 4: IHE CDA XML representation of Brand Substitute Allowed without using extension.

The advantage of the representation in Figure 4 is that no new namespace is required. However, the disadvantages are that the representation is not semantically

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correct, and that the meaning is not clear. This is because there is nothing in this model that states that Brand Substitution is allowed (Permission), only that it has occurred.

4.2 Architecture Challenges

The Australian National EHR infrastructure consists of a single domain XDS.b implementation. It has been customised to support a variation on the XML packaging specification which is an Australian Standard (AS 5821-2010) as well as local packaging and CDA content. A number of local high-level services have been added to address security and policy requirements. CDA content consists of zipped CDA packages for the five specified document types. This infrastructure has been developed and deployed in 18 months.

In parallel, commencing in 2010 a specification for electronic exchange of prescriptions (ETP) has been developed. This incorporates a bespoke repository with associated tailored upload and downloads services and CDA content for an ePrescription, pharmacy dispense information and feedback to the prescriber. This specification is complex (1200+ pages) and it is proving time consuming to reach agreement on scope and approach within government, as well as within the wider standards community. Since the commencement of this Australian specification, IHE has developed and released its XDS.b based specification for ETP and this is currently being implemented as part of the European EPSOS project.

4.3 Modeling

Early on in the development of the CDA specifications for the Australian national PCEHR, NeHTA realised that the content across the five specifications (Discharge summary, Specialist letter, e-Referral, Event summary and ETP) was similar but differently modelled. There was an issue of silos, where the requirements and the development of the CDA specifications happened in relative isolation. NeHTA re-evaluated their approach to developing the specifications and decided to use a logical model approach. This involved examining all of the requirements specifications and developing a single set of clinical models that met all of the requirements across all five specifications. These models were developed using the openEHR methodology and had wide clinical input using a web-based review process [8]. Once the models had been developed, the specifications were modified to use the same clinical models across all the specifications. This solved the problem of the same clinical information being modelled in different ways in different specifications. The other benefit of this approach was that CDA became a single output of the NeHTA tool chain. The logical models became the basis for the development of published documentation and the contents of the template packages that were the core of the PCEHR template service.

5 Discussion

There are specific issues that have had to be addressed in Australia in the use of CDA. The issue of localisation has meant that the CDA documents used in the PCEHR are heavily customised to fit into the overall eco-system that is the national EHR in Australia. This reduced the likelihood that the Australian documents will be useful outside the Australian context. This also limits the opportunity for CDA documents developed outside Australia to be useful in the context of the Australian EHR. This is an inevitable outcome of the governance and development of the content, and not a reflection on the fact that CDA was used. However, the learning gained about CDA implementation as applied to the general CDA principles will be applicable outside the Australian context.

The openEHR modelling approach has two major benefits for NeHTA development. The first benefit is that clinical content is developed using an approach that allows a wide range of clinical domain experts to become involved in the creation and review of the clinical content. The online approach to review of clinical content allows time poor clinicians to comment and suggest additions and changes to clinical models in an asynchronous way. There is no need to gather groups of clinicians together in a room which both saves money and time, and also allows for a much wider group of clinicians to participate.

The second benefit is that NeHTA have now developed a real tool chain approach with the logical models at the top (expressed as openEHR archetypes) and multiple artefacts being developed from the same source. This also means that other artefacts can be developed from the same source which provides consistency and traceability for users of the NeHTA specifications. NeHTA are currently looking at how to create artefacts that can be directly used in vendor systems for the Australian ehealth ecosystem.

In regard to the standards process, the CDA specifications developed for the national XDS based EHR are being handed over to the national standards body, Standards Australia, for consideration as standard's publications. This will provide a desirable level of stability and change governance for implementers. However, a number of issues have become apparent in this process:

1. a The sheer volume of documentation (thousands of pages) makes digestion and publication using a standards based approach challenging. Issues such as publication of code sets and XML examples in a standards compatible but computer readable manner, as well as references to external publications not under control of a standards body, are under active discussion.

2. b The CDA documents were developed over a number of years and the approach to agreement of data content and mapping of the data to CDA has evolved over time. This has led to some areas where similar content has been modelled differently. Iden-

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tification of these areas and agreement as to what should be modified for consistency across CDA documents is time consuming. In addition, impacts on current trial implementations in terms of backwards compatibility and interoperability have to be considered.

3. c Consideration needs to be given to having profiles of the documents that allow implementation at different levels of atomicity from Level 1 (PDF) to Level 3B (as explained in Table 1). In a point-to-point environment this allows for heterogeneous receiving software capability and a transition path to richer data exchange, but introduces the need to publish receiver endpoint capabilities on a per document type basis. This may be addressed by a proposed enhancement to the Endpoint Location Service that forms part of the SMD infrastructure.

4. d The CDA documents were developed principally with a focus on their use in a "point-to-share" (XDS repository) scenario and in particular on the General Practice desktop as the document source and consumer. The standards environment is also considering their use in the additional context of point-to-point document exchange and in the wider content of ehealth in general. This has led to the need to reconsider some data elements and mapping.

6 Conclusions

Development of clinical ehealth content for a national program presents significant challenges. Management of consistency of representation across time, development silos and different documents is difficult. The CDA standard has proven to be an effective standards base on which to undertake this work. However, the CDA standard has needed to be extended by both removing constraints, allowing more of the HL7 RIM to be expressed, and adding additional relationships. This has been able to be done within the extension methodology incorporated into the CDA standard.

The adoption of OpenEHR archetypes (also originally developed in Australia) as a top-level concept modelling approach has helped in addressing much of the potential for inconsistent representation across diverse specification development teams and over an extended development cycle of many years. The development of a complete tool chain from OpenEHR to CDA specification has proven extremely valuable and will enable future modifications and upgrades to be carried out in a relatively simple and consistent manner despite the complexity of the end-product CDA specifications. Development of future CDA documents will also be able to leverage this common superset schema. Current work is progressing on modifications that may be needed when moving CDA specifications from use in a point-to-share environment to a point-to-point document exchange paradigm. However, it has become clear that further standards work in this area is needed.

With the commencement of operation of the PCEHR on July 1, 2012, Australia will be able to start gathering information about the approach adopted. Will supporting zipped content only prove a problem? Will clinicians cope with the duality of narrative and atomic representations of clinical data? Will the uptake be sufficient to warrant further investment by both government and industry? Will system response times prove a problem? Will the security and privacy protections prove sufficient? These and many other questions can only be answered by gaining actual experience and Australia will in the vanguard of acquiring that knowledge on a national scale. However, CDA has proven to be an excellent standard on which to base this complex endeavour.

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